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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/214,679	12/30/1999	WALTER BRIEDEN	A32213-PCT	8348

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NEW YORK, NY 10112

EXAMINER

RAO, MANJUNATH N

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 09/18/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/214,679

Applicant(s)

BRIEDEN ET AL.

Examiner

Manjunath N Rao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 December 1999 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>18</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7-9-02 has been entered.

Claims 22-44 are still at issue and are present for examination.

Applicants' amendments/arguments filed on 7-9-02, paper No. 17, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

Sequence Compliance

Applicant is required to comply with the sequence rules by inserting the sequence identification numbers of all sequences recited within the claims and/or specification. For example, it is particularly noted that applicants recite amino acid or nucleic acid sequences without providing their respective SEQ ID NO on pages 8 and 28. See particularly 37 CFR 1.821(d).

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22, 25 and claims 28-32, 35-40 which depend from claims 22 or 25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a biologically pure culture of isolated microorganisms such as *K. oxytoca* PRS1, *K. Oxytoca* PRS1K17, *R. opacus* ID-622, *A. ramosus* ID620, *Bacillus sp.* ID-621, *K. planticola* ID-624, *K. pneumoniae* ID-625 or *Pseudomonas sp.* (DSM 11355) which are capable of utilizing and/or hydrolyzing (R)-3,3,3-trifluoro-2-hydroxy-2-methylpropionamide (THMP) as its sole source of nitrogen, a cell extract of these microorganism and a process of preparation of THMP using the amido hydrolase isolated from these microorganisms does not reasonably provide enablement for claiming any or all microorganisms (including variants and mutants) with the characteristic property of utilizing THMP as sole nitrogen source nor any protein capable of converting THMP. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the breadth of the claim(s), (2) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, and (7) the predictability or unpredictability of the art.

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Claims 22, 25 are so broad as to encompass any microorganism(s) capable of utilizing (and/or hydrolyzing) THMP as its sole source of nitrogen. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of microorganisms that are broadly encompassed by the claims.

First of all applicants are claiming all or any microorganisms that is capable of utilizing THMP in the form of racemate or of its optically active isomers as sole nitrogen source. The term microorganisms includes an enormously large group of organisms some of which are yet to be discovered. Furthermore, the group "microorganisms" is so diverse that it includes all types of bacteria known to man, all types of yeasts and fungi known to man, all types of blue green algae known to man and all types of microscopic animal cells that mostly comprise the division of protozoa. Thus by claiming "microorganisms", applicants are claiming an enormously large group of microorganisms for which a representative number itself would run into millions of microorganisms. Next, applicants have shown that the above characteristic feature is existent only in the deposited microorganisms which produce a specific amidohydrolase enzyme that imparts the capability of utilizing or hydrolyzing THMP, and since applicants have not shown that this above enzyme is produced by all species and strains of the deposited microorganisms or all or any other microorganisms, the claims encompass microorganisms that are capable of utilizing THMP as sole source of nitrogen by other mechanisms existing in nature. Applicants have also not shown that using THMP as sole source of nitrogen is only through the pathway that they have described i.e., through the action of the above amidohydrolase enzyme. In nature, microorganisms are known to be a highly varied group of organisms. For example, while some microorganisms produce ATP using a six carbon sugar such as glucose, some others produce the

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same ATP using a pentose sugar. Thus it is highly possible that there could be alternate pathways of using THMP as sole nitrogen source by microorganisms and applicants have shown the presence of only one such pathway. Furthermore, it is also well known in the art that the different strains within a single species or different species within a single genus can vary in their physical and biochemical characteristics. For example, not all strains of *E.coli* are known to cause food poisoning due to production of a heat stable toxin. As the above characteristic (i.e., use of THMP as sole nitrogen source) of the microorganism is dependent on the enzymes produced by the microorganisms, predictability of existence of alternate pathways for use of THMP as sole nitrogen source requires a knowledge of and guidance of the ways to identify and characterize specific microorganism in which the enzyme proteins' structure relates to its function. However, in this case the disclosure is limited to the few microorganisms which have been deposited in a culture collection.

While microbial isolation and identification techniques are known, it is not routine in the art to screen for multiple strains, as encompassed by the instant claims, and a reasonable expectation of success in obtaining the desired activity/utility are limited and the results of such identifications are unpredictable.

Examiner has concluded that the specification does not support the broad scope of the claims which encompass all microorganisms with the above characteristics based on the following analysis: (A, Breadth of the claim) Applicants have not shown that the assay they provide to identify the microorganism is suitable to test any microorganism, i.e., any bacteria, any yeast any fungi, any cyanobacteria or any protozoal cell. The assay they have provided is mainly for the bacterial cells. While applicants may argue that the assay they have provided is

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enough to identify any microorganism, Examiner disagrees with such an argument. This is because, just among bacteria there are different sub groups. For example there are aerobes and anaerobes. Anaerobic bacteria do not grow in the presence of air (or oxygen) and applicants have not shown as to how one skilled in the art would use their assay in the case of anaerobes. Similarly, Examiner can list a large number of groups of microorganisms which are highly diverse and no single method or assay would apply to all of them. However, providing such a list is beyond the scope of this rejection and impractical. B. (Nature of the invention)

Applicants have not shown that the mechanism involved (enzymatic pathway) in the use of THMP as sole source of nitrogen is universal in all microorganisms. Applicants have argued that the assay they have provided is quite enough to identify any microorganisms. Examiner respectfully disagrees. This is because of the nature of invention. It is well known in the art of the microbiology that microbes invariably have alternate pathways for making or breaking a compound. While applicants are claiming that they have provided an assay (which is based on assaying for the presence of an amidase) it is highly likely that alternate pathways may be present in nature, and because of this the assay provided by the applicants may not work on all microorganisms. C. (State of the prior art) The prior art is not rich in the above type of inventions i.e., the subject matter of the above invention is practiced by a small group of inventors and there is no information regarding the capability of all the different types of bacteria or yeasts or fungi or the cyanobacteria etc. in utilizing THMP as sole nitrogen source. Applicants have also not shown the above ability of any other type of bacteria or fungi or yeast or a cyanobacteria or a microscopic protozoan. Therefore, there are no examples of the above invention in the prior art. D. (level of ordinary skill) The specification does not provide a

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universal method that can be used by any one skilled in the art. This is because, while the specification simply provides the assay method that can be performed by one skilled in the art familiar with Bacilli, applicants have not provided enough guidance as to how one interested in isolating a thermophilic bacteria or psychrophilic bacteria or anaerobic bacteria or a fungi, a yeast or a microscopic protozoan would use the assay method for isolating the claimed microorganisms. The above groups of microorganisms have special culture requirements and applicants have not provided enough guidance such that their method can be used for testing any of the above microorganism. E (level of predictability in the art/ amount of direction provided by the inventor/existence of working examples) While predictability is quite straight forward in mechanical and electrical arts, it is highly unpredictable in bioscience arts. This aspect has been well understood in all court decisions. Therefore, while applicants claim that the assay they provide would be able to identify any microorganism, because of the complexity of the microbial cells, an assay that is applicable for one type of microorganism may be completely useless for another group. For example it has been acknowledged in *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, that in cases involving unpredictable factors, such as most chemical reactions and physiological activity, more may be required and in applications directed to inventions in art where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims, *In re Soll*, 97 F.2d 623, 624, 38 USPQ 189, 191 (CCPA 1938). F.(quantity of experimentation needed to make the invention) The specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful. This is because applicants have not provided a method or methods that can be used to identify any microorganism.

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Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any microorganism with the characteristic of utilizing THMP as sole source of nitrogen. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, identification of a microorganism having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

In response to the previous office action, applicants have traversed the above rejection arguing exhaustively at length and quoting from numerous court cases that the specification is indeed enabled and describes the methods for isolation of claimed microorganisms and also demonstrates that by working examples. In response Examiner has re-written the rejection addressing the *Wand* factors. Applicants also argue that while some experimentation may be necessary to isolate the microorganism, such experimentation cannot be undue. Examiner respectfully disagrees and reiterates that applicants are claiming “any or all microorganisms”. The term “microorganisms” is very broad and includes an extremely large number of bacterial species and strains, fungi, cyanobacteria, archaebacteria, and yeasts and protozoans. Furthermore applicants also include whole genus of microorganisms which comprise thousands of species and strains. While Examiner also agrees that some experimentation may be necessary for isolation of specific microorganisms within a small group, experimentation to identify such microorganisms from an extremely large group consisting of millions of microorganisms would constitute undue burden to one skilled in the art and even though applicants have shown the

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isolation of few specific strains they are not representative of the entire world of “microorganisms”. As stated in the previous office action the specification does not support the broad scope of the claims which encompass all microorganisms with the above characteristics. Therefore the above rejection is maintained.

Claims 22, 25 and claims 28-40 which depend from claims 22 or 25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. See previous office action for rejection.

In response to the previous office action applicants have traversed the above rejection and argue that the specification does describe the claimed microorganisms as only those that are capable of utilizing propionamide as the sole nitrogen source and that they have disclosed eight different microorganisms having the above characteristics. Applicants argue that they have not provided one but eight different microorganisms and hence the invention is fully described. Examiner respectfully disagrees. Applicants are not claiming just eight of the microorganisms that they have isolated but all microorganisms. Above claims are rejected because applicants are claiming an extremely large group of microorganisms and have not described a representative number of those microorganisms. The eight microorganisms described does not form a representative group of all hundreds and thousands of microorganisms which includes all bacteria, fungi, algae (cyanobacteria) and yeasts. Therefore the above rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22, 23, 25, 26, 41, 43 are rejected under 35 U.S.C. 102(a) as being anticipated by Hirrlinger et al. (J. Bacteriol., June 1996, Vol. 178(12):3501-3507). This rejection is based upon the public availability of a printed publication in this country before the invention by the applicant for a patent. Claims 22, 23, 25, 26, 41, 43 of the instant application are drawn to a biologically pure culture of microorganism wherein said microorganism utilizes/hydrolyzes propionamide of formula VI in the form of the racemate or of its optically active isomers as the sole nitrogen source and wherein the microorganism is selected from the group consisting *Rhodococcus*, *Arthrobacter*, *Bacillus*, *Klebsiella* and *Pseudomonas*, a cell extract of such microorganisms. Hirrlinger disclose the pure culture and cell extract of one such microorganism, *Rhodococcus* MP50 which uses as sole nitrogen source or hydrolyzes enantioselectively 2-aryl-propionamides (see the entire document). Therefore Hirrlinger et al. anticipate claims 22, 23, 25, 26, 41, 43 of this application as written. Applicants may argue that Examiner has not provided a reference which teaches every element of the rejected claims. In that regard applicants may argue that the reference does not explicitly teach that the microorganism in the reference uses the propionamide of formula VI as sole nitrogen source or that it hydrolyzes the propionamide of formula VI. However, such argument will not be persuasive.

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to overcome the rejection because based on the characteristic feature of the microorganism to use 2-arylpripionamide as sole source of nitrogen and also based on its ability to hydrolyze the above compound, Examiner takes the position, that the microorganism inherently has the characteristic of using or hydrolyzing the propionamide of formula VI even though the reference does not teach the same. Furthermore, since the Office does not have the facilities for examining and comparing applicants' microorganism with the microorganism of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the microorganism of the prior art does not possess the same material structural and functional characteristics of the claimed microorganism). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

Claims 22, 23, 24, 25, 26, 41, 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Hashimoto et al. (*Biochimica et Biophysica Acta*, 1991, Vol. 1088:225-233). This rejection is based upon the public availability of a printed publication in this country more than one year prior to the date of application for patent in the United States. Claims 22, 23, 25, 26, 41, 43 of the instant application are drawn to a biologically pure culture of microorganism wherein said microorganism utilizes/hydrolyzes propionamide of formula VI in the form of the racemate or of its optically active isomers as the sole nitrogen source and wherein the microorganism is selected from the group consisting *Rhodococcus*, *Arthrobacter*, *Bacillus*, *Klebsiella* and *Pseudomonas*, a cell extract of such microorganisms. Hashimoto et al. disclose the pure culture and cell extract of one such microorganism, *Rhodococcus* species which hydrolyzes propionamides (see the entire document). Therefore Hashimoto et al. anticipate claims 22, 23, 25, 26, 41, 43 of this application as written. Applicants may argue that Examiner

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has not provided a reference which teaches every element of the rejected claims. In that regard applicants may argue that the reference does not explicitly teach that the microorganism in the reference uses the racemate forms of propionamide of formula VI as sole nitrogen source or that it hydrolyzes the same. However, such argument will not be persuasive to overcome the rejection because based on the characteristic feature of the microorganism to hydrolyze propionamide, Examiner takes the position, that the microorganism inherently has the characteristic feature of using or hydrolyzing the racemate form of propionamide of formula VI even though the reference does not teach the same. Examiner concludes that the amidase enzyme isolated from the microorganism in the reference and the enzyme referred to in the application are the same. Furthermore, since the Office does not have the facilities for examining and comparing applicants' microorganism with the microorganism of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the microorganism of the prior art does not possess the same material structural and functional characteristics of the claimed microorganism). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

Claim Rejections - 35 USC § 102/103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 22-34, 36-44 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Dominique et al. (EP 0433117 A1, 6-19-1991 see entire document). This rejection is based upon the public availability of a printed publication in this country for more than one year before the invention by the applicant for a patent. Claims 22-34, 36-44 of the instant application are drawn to a biologically pure culture of microorganism wherein said microorganism utilizes/hydrolyzes propionamide of formula VI in the form of the racemate or of its optically active isomers as the sole nitrogen source and wherein the microorganism containing a polynucleotide (with SEQ ID NO:1 or any polynucleotide which hybridizes to SEQ ID NO:1 under stringent conditions and encodes a stereospecific amidohydrolase) encoding a polypeptide with SEQ ID NO:2, having aminohydrolase activity and wherein such activity hydrolyzes the propionamide of the formula VI, is selected from the group consisting *Rhodococcus*, *Arthrobacter*, *Bacillus*, *Klebsiella* and *Pseudomonas*, a cell extract of such microorganisms and the use of such microorganisms or their cell extract for the preparation of the compounds of the formula I, II, VII, VIII by converting propionamide of the formula VI followed by their isolation. Dominique et al. disclose the pure culture and cell extract of one such microorganism, *Rhodococcus* which hydrolyzes enantioselectively 2-aryl-propionamides (see the entire document). Therefore Dominique et al. anticipate claims 22, 23, 25, 26, 41, 43 of this application as written. In the alternative, the above reference renders claims 22-34, 36-44 obvious under 35 U.S.C. 103(a). This is because the above reference teaches a method of preparation of a stereoisomer of an organic acid from corresponding racemic amide such as 2-aryl-propionamide using the amidohydrolase isolated from, or cell extract or the microorganism *Rhodococcus*. With this teaching in hand, it would

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have been obvious to one of ordinary skill in the art to use the same microorganism/cell extract or enzyme for preparation of the compounds of the formula I, II, VII, VIII by converting propionamide of the formula VI. One of ordinary skill in the art would be motivated to do so as such compounds have industrial applications and their synthesis by other techniques are less economical. One of ordinary skill in the art would have a reasonable expectation of success since Dominique et al. provide the microorganism, the purified enzyme and also demonstrate one such application. Therefore the above reference either anticipates or renders above claims *prima facie* obvious to one of ordinary skill in the art. Applicants may argue that Examiner has not provided a reference which teaches every element of the rejected claims. In that regard applicants may argue that the reference does not explicitly teach that the microorganism in the reference uses the propionamide of formula VI as sole nitrogen source or that it would be able to make the compounds of the formula I, II, VII, VIII by converting propionamide of the formula VI or that the microorganism in the reference is not the same deposited strain or that the microorganism in the reference contains the polynucleotide with SEQ ID NO:1 encoding the amidohydrolase with SEQ ID NO:2 etc. However, such arguments will not be persuasive to overcome the rejection because based on the characteristic feature of the microorganism to hydrolyze 2-arylpropionamide, Examiner takes the position, that the microorganism of the reference inherently has all the above characteristics even though the reference does not teach the same and that the microorganism in the reference is actually the same as in the instant application even though it is identified by a different strain and deposit number and that it inherently contains the same polynucleotide sequence SEQ ID NO:1 encoding the amidohydrolase with SEQ ID NO:2. Furthermore, since the Office does not have the facilities

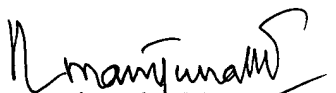
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for examining and comparing applicants' microorganism with the microorganism of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the microorganism of the prior art does not possess the same material structural and functional characteristics of the claimed microorganism). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath N. Rao whose telephone number is 703-306-5681. The examiner can normally be reached on 7.30 a.m. to 4.00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0196.



Manjunath N. Rao Ph.D.
Patent Examiner, A.U. 1652
September 17, 2002